



06/13/2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1/5

JUN 13 2013

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Brain Anson
L. Perrigo Company
515 Eastern Avenue
Allegan, MI 49010

Subject: Label Notification(s) for Pesticide Registration 98-10

Dear Mr. Anson:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated for May 9, 2013 for:

Alternate Brand Name

Family Wellness Home Lice Control Spray

The Registration Division (RD) has conducted a review of this request for applicability Under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

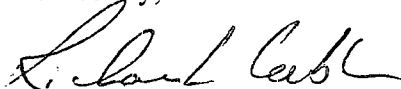
EPA Registration Number: 71-1

0.5% Permethrin Aerosol Spray

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail at banks.melody@epa.gov.

Sincerely,



Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)

2/5

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 71-1-40020	2. EPA Product Manager Mr. Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 0.5% Permethrin aerosol spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) L. Perrigo Company 515 Eastern Avenue Allegan, MI 49010 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 71-1 Product Name Good Sense In-Home Bedding Spray Lice Tr	

NOTIFICATION
JUN 13 2013

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand name: Per 40 CFR 152.46 and PR Notice 98-10, this is to notify EPA of the addition of a new alternate brand name to the brand names already under Perrigo. Labeling meets the requirements of 40 CFR 156.01. (See attachment for additional information)

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 oz (142 g)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Brian Anson		Title Reg Affairs Project Mgr	Telephone No. (Include Area Code) 269-673-1375
2. Signature 			6. Date Application Received (Stamped)
3. Title Regulatory Affairs Project Manager			
4. Typed Name Brian Anson			
5. Date May 9, 2013			

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

A collection of 15 small, stylized line drawings of various birds, including shorebirds, waterfowl, and songbirds, arranged in a grid-like fashion.

NO PRINT / NO COLOR AREA

NO COPY AREA

This product is Step 3 of a three step lice control system that includes a shampoo as Step 1 and a combing gel as Step 2.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS
CAUTION: Harmful if swallowed or absorbed through skin. Avoid inhalation of spray mist. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food and foodstuffs.

PHYSICAL OR CHEMICAL HAZARDS
Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

FIRST AID	
Call a Poison Control Center or doctor immediately for treatment advice. Have product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
If swallowed:	<ul style="list-style-type: none">• Immediately call a Poison Control Center or doctor.• Do not induce vomiting unless told to do so by a Poison Control Center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
NOTE TO PHYSICIAN Contains petroleum distillate - vomiting may cause aspiration pneumonia. EPA Reg. No. 71-3-40020 EPA Est. No. See Bottom or Top of Can	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Remove pets and birds and cover fish aquarium before spraying or surface applications. This product is not for use on humans. If lice infestation occurs on humans, use a product labeled for use on humans. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry.

SHAKE WELL BEFORE USING

Remove protective cap. Hold container upright and spray from a distance of 8-10 inches. Individuals with asthma or severe allergies should consult their doctor before using this product and have someone else apply this product.

To kill lice and loose eggs: Spray in an inconspicuous area to test for possible staining or discoloration. Repeat again after drying, then proceed to spray entire area to be treated. Hold container upright with nozzle away from you. Sweep valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray to the point of dampness but not run-off. Spray only three articles and parts of bedding including mattresses and furniture that cannot be either laundered or dry-cleaned. Do not use on electronics, sheets or clothing. Always all sprayed articles to dry thoroughly before each use.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area away from children and pets and away from heat, sparks and open flame. Do not transport or store below 32°F (0°C).
Container disposal: Do not puncture or incinerate. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-4-LEADUP for disposal instructions. Never place unused product down any drain or outdoor drain.

NOTICE: Purchaser assumes all responsibility for safety and use not to accordance with directions.

DISTRIBUTED BY: FAMILY DOLLAR SERVICES, INC., 10401 MONROE RD, MATTHEWS, NC 28105 USA

SKU 0940238 V-476



3225103212 7

FAMILY

wellness



Home Lice Control Spray

3 CONTROL

- Not For Use On Humans
- For Bedding And Furniture
- Kills Lice And Their Eggs On Mattresses-Furniture Car Interiors Other Non-Washable Items

ACTIVE INGREDIENT:	
Permethrin	0.50%
OTHER INGREDIENTS:	
	99.50%
	100.00%
cis/trans ratio: Min. 35% (+/-) cis and Max. 65% (+/-) trans.	
†Contains Petroleum distillate	

KEEP OUT OF REACH OF CHILDREN
CAUTION:
See Side Panel for Additional Precautions

NET WT 5 OZ (142 g)

NO COPY AREA

NO COPY AREA